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EXAMINER	
YAO, LEI	

ART UNIT	PAPER NUMBER
1642	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/781,659	ITOH ET AL.	
	Examiner	Art Unit	
	Lei Yao, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *18 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,5-7,9 and 11-15* is/are pending in the application.

4a) Of the above claim(s) *9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,5-7 and 11-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09763985.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to Arguments and Amendments

The Amendment filed on 7/18/2007 in response to the previous Non-Final Office Action (1/19/2007) is acknowledged and has been entered.

Claims 2, 3, 5-7, 9, 11-15 are pending. Claim 9 has been withdrawn for non-elected invention. Claims 2, 3, 5-7, and 11-15 to the extent of SEQ ID NO: 3 are under consideration.

The following office action contains NEW GROUNDS of rejection-based on amendment to the claims.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of Japan 242660/1998 has been filed in parent Application No, 09/9763985. The English translation of this foreign application Japan 242660 is received in this application.

Rejections Withdrawn

1. The rejection of 2-8 and 11-15 under *35 U.S.C.101* because the claimed invention is directed to non-statutory subjection matter is withdrawn in view of the amendments to the claims or cancellation of the claims.

2. The rejection of claims 12-13, and 15 under 35 U.S.C. 112, second paragraph, as being insufficient antecedent basis of the claims is withdrawn in view of the amendments to the claims.

3. The rejection of claims 2-8 and 11-15 under 35 U.S.C. 102(a) as being anticipated by Yang et al., (Cancer Res, 59:4056-4063, Aug, 15,1999) is withdrawn in view of submission of English translation of foreign applicant Japan 242660/1998 (8/28/1998).

4. The provisional rejection of claims 2-5 and 11-15 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11, 19 and 23 of copending Application No. 10788016 is withdrawn in view of abandonment of the application.

Response to Arguments and Amendments

Restriction requirement

Applicant has elected without traverse of group II (claims 2-15) with SEQ ID NO: 3 in the reply to the restriction requirement filed on 10/19/06. Now, applicant argue that the restriction is improper because SEQ ID NO: 3-52 are parts of the SEQ ID NO: 2 and search SEQ ID NO: 2 reveal the prior art relevant to the present invention. This has been carefully considered but is deemed not to be persuasive. SEQ ID NO: 2 is large protein containing more than 900 amino acids, while all sequences of SEQ ID NO: 3-52 are small synthetic peptides, which are part of the SEQ ID NO: 2 and no significantly overlapped sequences among them. Each of SEQ ID NOs is a unique and separately patentable sequence, requiring different search of the prior art. Searching all of the sequences in a single patent application would constitute an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches. For this reason, the restriction requirement is deemed to be proper and is adhered to. The requirement is therefore made FINAL. Therefore, only elected SEQ ID NO: 3 is/was examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the **first paragraph of 35 U.S.C. 112:**

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Drawn to Written Description:

Claims 2, 3, 5-7, and 11-15 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention as stated below.

The Claims are broadly drawn to tumor antigen peptide that is a partial peptide of SEQ ID NO: 2 comprising an amino cid sequence shown by SEQ ID NO: 3 (10 amino acids at position 109-118 of SEQ ID NO: 2), or derivatives of tumor antigen peptides having amino acid substitution at position 2 and/or the C-terminus in the peptide of SEQ ID NO: 3, which bind to an HLA antigen and is recognized by cytotoxic T-lymphocytes. Thus, the claims are inclusive of a genus of tumor antigen peptides that can be any fragment of SEQ ID NO: 2 comprising an amino acid sequence of SEQ ID NO: 3 and derivative thereof with amino acid substitutions of SEQ ID NO: 3. The claimed reciting an amino acid sequence of SEQ ID NO: 3 could be as small as only two amino acid peptide (claims 4-5). The specification also asserts that the amino acid in the SEQ ID NO: 3 can be substituted at position 2 and C-terminus. Thus, the claims encompass a significant structural and functional dissimilarity and diversity as compared to this peptide consisting of SEQ ID NO: 3. The specification as filed does not provide adequate written description support for the claimed tumor antigen peptide that are partial peptide of SEQ ID NO: 2 comprising an amino acid sequence of SEQ ID NO: 3 or its derivative.

The specification on page 22 discloses a method for identifying tumor antigen peptide and states that if the candidate induces CTL that specifically recognized the HLA-antigen-presenting cells.....indicated that the particular candidate peptide may function as tumor antigen peptide. However, the specification, page 62-64, example 6, only reasonably conveys that the peptides of SEQ ID NO: 3 and 6 (non-elected invention), which are fragments of SEQ ID NO: 2 at positions 109-118 and 315-323 bind to HLA-A24 antigen and be recognized by cytotoxic T-lymphocytes, no derivatives of SEQ ID NO: 3 having such tumor antigen function as the peptide of SEQ ID NO: 3 were described.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common the genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristic, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613".

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., F.3d ,2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The mechanism of binding peptide to HLA and being recognized by T-lymphocyte is well known by one skilled in the art. Every peptide against which an immune response can be generated must contain some residues that contribute to biding to the clefts of MHC (HLA-2) and must also contain other residues that project from the clefts, where they are recognized by T-cells. The peptide that binds to HLA molecules shares structural feature that promote this interaction (see Abbas et al., Cellular and Molecular Immunology, 4th edition. 2000, page71-72). The instant specification fails to provide sufficient descriptive information, such as definitive or shared structural or functional features that are common to the claimed tumor antigen peptide for binding of HLA and being recognized by T-lymphocytes. That is, the specification provides neither a representative number of tumor peptide antigens of derivative of SEQ ID NO: 3 or partial peptide of SEQ ID NO: 2 that encompass the genus that reveal the roles of tumor antigen nor does it provide a description of structural features that are common to the peptide of SEQ ID NO: 3 is associated with HLA-A24 binding and being recognized by cytotoxic T-lymphocytes. Described peptide of SEQ ID NO: 6 does not share a common structure or sequence with SEQ ID NO: 3. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the

disclosure of amino acid sequence of SE ID NO: 3 is insufficient to describe the genus of partial peptide of SEQ ID NO: 2. Thus, one of skill in the art would reasonably conclude that the inventor(s), at the time the application was filed, did not have possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure(s) and functional attribute(s) of the encompassed genus of tumor antigen peptide, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only tumor antigen peptide consisting of amino acid sequence of SEQ ID NO: 3, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112 paragraph 1" Written Description" Requirement. Applicant is invited to point to clear support or specific examples of the claimed invention in the specification as filed.

The response filed 7/18/2007 has been carefully considered but is deemed not to be persuasive. Applicants on page 7 argues that the Office unreasonably interpreting the claims as the following:

> "sequence of SEQ ID NO: 3" can be as short as two amino acids" and "the claim recites "comprising an amino acid sequence according to claim 3". Thus, the entirety of the amino acid sequence of claim 3 (may mean SEQ ID NO: 3) must be included in the claimed peptide.

In response, the Office agrees with applicant on that the entirety of the amino acid sequence of SEQ ID NO: 3 could be included in the claimed peptide. However, the claims also encompass the peptides more than SEQ ID NO: 3, that is, a genus of peptides that could longer or shorter than the peptide of SEQ ID NO: 3. For example, claim 2 recites " the peptide comprises an amino acid sequence of SEQ ID NO: 3 that reads any amino acid sequence or peptide within SEQ ID NO: 3, which could be as small as two amino acid peptide. The Office suggests to amend the claims to consist of the amino acid sequence of SEQ ID NO: 3 (close language) or

comprise the amino acid sequence of SEQ ID NO: 3 (open language) to obviate the rejection on this issue.

Applicant on page 7 further argues "the claimed peptide must exhibit a function of binding HLA-A24 or HLA-A2 and the specification specifies particular portions of SEQ ID NO: 2" and also states "one of ordinary skill in the art can understand, even in the absence of specific experimental results, those peptides having the requisite "motifs" bind to an HLA antigen". In response, claims encompass a genus of peptides having the function of binding HLA-A24 or HLA-A2. As stated in the rejection above, the specification only teaches the peptides of SEQ ID NO: 3 that is a fragment of SEQ ID NO: 2 at positions 109-118 binding to HLA-A24 antigen and be recognized by cytotoxic T-lymphocytes, no derivatives or variants of SEQ ID NO: 3 having such tumor antigen function as the peptide of SEQ ID NO: 3 are described in the specification. Thus application does not describe the genus of the peptides that are variants or derivatives of SEQ ID NO: 3 as claimed because the variants or derivatives of SEQ ID NO: 3 having the same function as the peptide of SEQ ID NO: 3 would be subjected to undue experimentations for the claimed function.

Applicant, on the bridging page 7-8, further argues "the protein consisting of the amino acid sequence of SEQ ID NO: 2 indeed functions as a tumor antigen protein is shown in working Examples 1 and 2" and then on the first paragraph of page 8, applicant cites a few articles published and argues "the state of the art at the time the invention was made as such that there are certain rules (motifs) in the sequences of antigen peptides that bind to and presented by HLA antigens". In response, the entire protein of SEQ ID NO: 2 having a function as a tumor antigen is known in the art and proved by application as described in examples 1-2. However, current invention, applicant is claiming a portion of the protein, a small peptide at positions 109-118 (SEQ ID NO: 3) and its variants or derivatives comprising the 10 amino acids having the same function. Although the cited articles by applicant, for example, Kubo et al., teach that the peptides for HLA-A24 binding are often 8-12 amino acids in length and displayed anchor residues at position 2 and C-terminal, Kubo et al., disclose that these binding peptides are eluted from affinity purified class I as mixture and sequenced and determined the binding capacity of motif containing the

polyalanine peptide. However, the claimed variants or derivatives of SEQ ID NO: 3 (position of 109-118 of SEQ ID NO: 2) have not been proved having such functions of class I HLA-A24 or HLA-A2 binding or eluted from any of the mixtures of the class I molecules. Therefore, applicant has not convinced one skilled in the art that the variants or derivatives of SEQ ID NO: 3 with amino acid substitution at position 2 or C-terminal recited in claim 6 based on the cited papers would have claimed function because applicant has not provided enough species of the variants or derivatives of SEQ ID NO: 3 that could perform claimed function of HLA-A24 or HLA-2A binding. Applicant has not provided any peptide comprising SEQ ID NO: 3 except the entire protein of SEQ ID NO: 2 having such function. One skilled in the art would conclude the applicant, as the time of filing the application, has the possession of claimed invention. Thus, Applicant's argument has not been found persuasive, and the rejection is maintained as reason of the record.

Drawn to Enablement

Claims 2, 3, 5-7, and 11-15 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a tumor antigen peptide consisting of the amino acid SEQ ID NO: 3 does not reasonably provide for the other partial peptide of a protein having a SEQ ID NO: 2 or derivative thereof of the SEQ ID NO: 3 is most nearly connected, to use the invention commensurate in scope with these claims as stated below.

The factor considered when determining if the disclosure satisfies the enablement requirement and whether any is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of necessary experimentation claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re wands,* 858 F.2d 731, 737.8 USPQ2d 1400, 1404 (Fed. Cir.1988).

The claims are broadly drawn to a tumor antigen peptide is a partial peptide of SEQ ID NO: 2 comprising a peptide having an amino acid sequence (could be as small as only two amino acid peptide) of SEQ ID NO: 3 or derivative thereof that binds to and is recognized by HLA-A24 restricted T-lymphocytes. To satisfy the requirement of 112, 1st paragraph, it is necessary that the specification provide an enabling disclosure of how to make and use a claimed invention. Thus, it would be expected that one of skill in the art would be able to make and use the claimed peptide as a tumor antigen, which is recognized and activated by T-lymphocytes.

The specification on page 22 discloses a method for identifying tumor antigen peptide and states that if the candidate induces CTL that specifically recognized the HLA-antigen-presenting cells.....indicated that the particular candidate peptide may function as tumor antigen peptide. However, the specification, page 62-64, example 6, only reasonably conveys one

peptide of SEQ ID NO: 3 having tumor antigen activity and is recognized by HLA-A24-restricted T-cells, no derivatives of SEQ ID NO: 3 or other claimed partial peptide of SEQ ID NO: 2 comprising SEQ ID NO: 3 could bind to HLA-A24 and are recognized by T-lymphocytes. Again as discussed above, every peptide against which an immune response can be generated must contain some residues that contribute to binding to the clefts of MHC (HLA-2) and must also contain other residues that project from the clefts, where they are recognized by T-cells. The peptide that binds to HLA molecules shares structural feature that promote this interaction (see Abbas et al., Cellular and Molecular Immunology, 4th edition. 2000, page71-72). The specification does not provide such common structure in the peptide of SEQ ID NO: 3 that enable the claimed peptide for the binding of HLA-A24 and being recognized by T-cells. In the absence of this minimally shared structure, applicant would have to screen a large amount of peptide fragment of SEQ ID NO: 2 to determine whether a peptide can be a tumor antigen based on the ability of binding to HLA-A24 and being recognized by T-lymphocyte. Yang et al., (Cancer Res, 59:4056-4063, Aug, 15,1999) teach a protein SART3 that have the amino acid sequence of SEQ ID NO: 2. Yang et al., teach that peptides, SART3 $_{109-118}$ and SART3 $_{315-323}$ as partial peptides of SEQ ID NO: 2 at position 109-118 (identical to SEQ ID NO: 3) and position 315-323 having an ability to bind to HLA-A24 and be recognized by T-lymphocyte. Yang et al., teach that the rest peptide fragments of the SART3 protein have much less or no binding to HLA-A24 and not being recognized or activated by T cells. Thus, the reference by Yang et al., clearly teach that NOT every partial peptide of the protein (SEQ ID NO: 2) has an ability to bind to an HLA-A24 and be recognized by cytotoxic T-lymphocytes.

In view of the lack of guidance, lack of examples, and lack of predictability associated with regard to the structure to bind to HLA-A24 and be recognized by cytotoxic T-lymphocytes, one skilled in the art would be forced into under experimentation in order to practice the broadly claimed invention.

The response filed 7/18/2007 has been carefully considered but is deemed not to be persuasive. Applicant on page 9 again argues that the Office unreasonably interprets the claims and mystify Example 6 of the specification as the following:

> Example 6 describes an experiment that demonstrates that two particular peptide portions of SEQ ID NO: 2 bind to CTL in an HLA-A24-restricted manner, since they stimulate interferon synthesis in HLA-A24 expressing cells, but not in cells that do no express HLA-A24. (See, the bottom of page 63 of the specification.)

In response, regarding to the interpretation of claims, applicant's argument has been set forth above (argument for written description). The Office would like to clarify and further discuses the statement for example 6 set forth in the rejection. The specification, page 62-64, example 6, only reasonably conveys one peptide of SEQ ID NO: 3 (position 109-118 of SEQ ID NO: 2) having tumor antigen activity and is recognized by HLA-A24-restricted T-cells, no derivatives of SEQ ID NO: 3 or other claimed partial peptide of SEQ ID NO: 2 comprising SEQ ID NO: 3 is tested for binding HLA-A24 and are recognized by T-lymphocytes. The SEQ ID Nos disclosed in other examples and SEQ ID NO: 6 (position 315-323 of SEQ ID NO: 2) in example 6 are not the variants of elected SEQ ID NO: 3 and would not be examined in current prosecution. Thus, once

again, because applicant has not provided objective evidence for claimed variants or derivatives of the peptides of SEQ ID NO: 3 having a function of binding to HLA-A24 or HLA-A2 and being recognized by cytotoxic T-lymphocytes, one skilled in the art would not know how to make and use claimed peptide as tumor antigen being recognized by cytotoxic T lymphocytes.

Applicant on page 9, last paragraph, states that the specification discloses how to synthesize peptide of the invention and how to test them for the activity in binding HLA-A24. In response, because claimed invention is product, not a method of making the product, disclosing how to make and test is not the same meaning of how to use the claimed invention. Because the functions of claimed peptides have not been tested positive as claimed and no objective evidence has been provided a quantity of undue experimentations would be required. Thus, Applicant's argument has not been found persuasive, and the rejection is maintained as reason of the record.

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Rejection under 35 USC § 102

Claims 2, 3, 5-7 and 11-15 remain rejected under 35 U.S.C. 102(b) as being anticipated Uniprot-7.2 database Accession No, Q15020 and Nagase et al., (DNA Res, 2:167-174, 1995) as evidenced by sequence search and alignment as stated below.

Uniprot database, Q15020, and Nagase et al., (KIAA0156 in table 1) disclose a protein comprising SEQ ID NO: 3 as evidenced by attached sequence alignment (exhibit A). Since the protein disclosed in Unipro database and Nagase et al., is identical to the claimed peptide, it is inherent that the protein would bind to HLA antigen and be recognized by cytotoxic T-lymphocytes.

The response filed 7/18/2007 has been carefully considered but is deemed not to be persuasive. Applicant on page 10 argues;

> Nagase et al. discloses the entirety of SEQ ID NO: 2. However, the reference is silent with respect to the HLA-A24 binding activity of the protein and in particular does not direct one of ordinary skill in the art to the particular peptides recited in the present claims. See, for example, In re Petering, 133 USPQ 175 (CCPA 1972). Thus, the presently claimed invention is not anticipated by Nagase et al. and the instant rejection should be withdrawn.

In response, first, claimed invention reciting partial peptide of SEQ ID NO: 2 comprising an amino acid sequence of SEQ ID NO: 3 reads on entirety of the amino acid sequence of SEQ ID NO: 2 because of the open language "comprising". Thus, the protein disclosed by Nagase et al., would

inherently have the same property and the function of HLA-A24 or HLA-A2 binding as claimed peptide even reference is silent with respect to the HLA-A24 binding activity. **Thus,** applicant's argument has not been found persuasive, and the rejection is maintained as reason of the record.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Copending application 10505955:

Claims 2, 3, 5 and 11-15 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 35 and 43 of copending Application No. 10505955 ('955). Although the conflicting claims are not identical, they are not patentably distinct from each other and rejection stated as below.

Claims 2-5 and 12 are drawn to a tumor antigen peptide that is partial peptide of a protein having amino acid sequence of SEQ ID NO: 2 or the peptide comprising an amino acid sequence of SEQ ID NO: 3. Claims 11-15 are drawn to a pharmaceutical composition and diagnostic agent having active component of SEQ ID NO: 3 or a partial peptide of SEQ ID NO: 2.

Claim 35 and 43 of copending application 10505955 ('955) teaches pharmaceutical composition having an antigen peptide represented by SEQ ID NOs:1-30. The amino acid sequence of SEQ ID NO: 21 in the copending application '955 is identical to instant claimed peptide (SEQ ID NO: 3) and is a partial peptide of SEQ ID NO: 2.

Claims 35 and 43 of the copending application '955 do not teach that the peptide binds to HLA-A24 and is recognized by cytotoxic T-lymphocytes. However, both sets of claim are directed to tumor antigen peptide or the peptide containing pharmaceutical composition. The difference between the two sets of claims is that the claims of copending application do not encompasses intended use to bind to HLA-A24 and be recognized by T-lymphocytes and the peptide is only presented in the pharmaceutical composition, which would not be given any patentable weight. Thus the only difference between the two sets of claims is intent use of the peptide. Because both set of the claims encompass an identical peptide alone or in the pharmaceutical composition the claim(s) are obvious over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant argues the application is not owned by the same entity as the present application. In response, the double patenting rejection is not limited to the same invention claimed by the same inventive entities, the two copending applications claiming the same invention, which have ONE common inventor, no common assignee, are also subjected to the double patenting rejection. Applicant is directed to MPEP 804, especially chart I-A, for the detailed. Thus, Applicant's argument has not been found persuasive, and the rejection is maintained for reason of the record.

The following is a New Ground of rejection-based on the amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim is indefinite because the term "a derivative of the tumor antigen peptide of claim 5 that comprises an amino acid sequence of any one of SEQ ID NO: 53-64 " is not clear. It is not clear how the tumor antigen in claim 5 that recite elected SEQ ID NO: 3, could comprise or further comprise other SEQ ID NOs. Clarification or correction is required.

2. Claim recites the limitation "a derivative of the tumor antigen peptide of claim 5". There is insufficient antecedent basis for this limitation in the claim. Claim 5 depends on claims 3, which depends on claim 2, none of the claims recites or directs to a derivative of the tumor antigen peptide. Clarification is required. See MPEP below.

The lack of clarity could arise where a claim refers to "said lever" or "the lever," where the claim contains no earlier recitation or limitation of a lever and where it would be unclear as to what element the limitation was making reference. Similarly, if two different levers are recited

earlier in the claim, the recitation of "said lever" in the same or subsequent claim would be unclear where it is uncertain which of the two levers was intended (See MPEP 2173.05).

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao,
Examiner
Art Unit 1642

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SHANON FOLEY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600